NIOSH recommends that health care facilities use safer medical devices to protect workers from needlestick and other sharps injuries.
Since the passage of the Needlestick Safety and Prevention Act in 2000 and the subsequent revision of the OSHA Bloodborne Pathogen Standard, all health care facilities are required to use safer medical devices.

Safer Medical Device Implementation in Health Care Facilities

Sharing Lessons Learned

NIOSH has asked a small number of health care facilities to share their experiences on how they implemented safer medical devices in their settings. These facilities have agreed to describe how each step was accomplished, and also to discuss the barriers they encountered and how they were resolved, and most importantly, lessons learned.

DISCLAIMER: Provision of this report by NIOSH does not constitute endorsement of the views expressed or recommendation for the use of any commercial product, commodity or service mentioned. The opinions and conclusions expressed are those of the authors and not necessarily those of NIOSH. More reports on Safer Medical Device Implementation in Health Care Settings can be found at http://www.cdc.gov/niosh/topics/bbp/safer/

Phase 3 Report: Identify and Screen Safer Medical Devices

Our health-care system is a nonprofit, consumer-governed system that coordinates care and coverage. It provides care to nearly 600,000 people in the Western United States. Our system includes a nationally recognized research center, charitable community foundation, medical centers, specialty centers, and hospitals. In addition, we provide home health care services to our members and skilled nursing services through our long-term care facility. We own and operate our own laboratory. We employ nearly 10,000 staff including an associated 1,050 physician group practice. There are approximately 4,500 clinical staff who use sharp devices.

Our organization decided to trial IV catheters as our first safer medical device based upon the high risk of disease transmission associated with these devices. The next step in the process was to identify specific brands and product names of safer IV catheters to consider for evaluation and possible implementation. This was a two-step process: 1) identifying the manufacturers and their products and 2) physically examining the safer IV catheters to ensure their appropriateness for specific clinical settings.

Description of the process our sharps injury prevention team used in identifying safer IV Catheter devices (Step 1)

The process our sharps injury prevention team used to identify safer IV catheters was multifold. It included:

1. Division of research work amongst committee members to identify safer IV catheters. Material Management and Employee Health/Infection Control primarily completed the responsibility for this task.

2. Drawing upon committee members' past experiences and knowledge of safer IV catheter devices that were available.

3. Using product information obtained from professional meetings with IV catheter manufacturer representatives.

4. Development of a pre-pilot IV catheter evaluation form to be used by the committee to pre-screen identified IV catheters before trial by the front line staff.

5. Commercial product availability.

Description of where our sharps injury prevention team obtained information about available IV catheter devices and what this information included (Step 1)

Our sharps injury prevention team obtained information about IV catheters from several different sources. These included:

1. Material management review of safer IV catheter products available on our contracted buying agreement. There were three manufacturers with IV catheter products.

2. Employee Health review of safer medical devices sites on the Internet. The most helpful site was National Alliance for the Primary Prevention of Sharps Injuries (NAPPSI) at http://www.nappsi.org/ .

3. Employee Health, Infection Control, and staff member provision of names of IV catheters that they obtained by attending conferences, safety fairs, and professional meetings. Employee Health and Infection Control obtained feedback, in their respective professional meetings, on IV catheters already in use at local institutions.

4. Review of information on five safer IV catheter devices, which had been provided by manufacturer representatives to Employee Health and Infection Control.

5. Literature search to determine if any infections were related to use of a specific safer IV catheter.

Criteria used in identifying the manufacturers and their products to decide which IV catheter devices should be screened for possible pilot testing (Step 1)

Our sharps injury prevention team used the following criteria to determine which IV catheter devices should be screened for pilot testing:

1. Availability of the product for use in a large institution. Our yearly average usage was approximately 94,050 catheters.

2. Availability of different sizes of catheter. We specifically were interested in a 24-gauge catheter for use in pediatrics and for patients with fragile veins.

3. Availability of vendor support for training. Approximately 650 staff, over a broad geographic area, needed to be trained on the device that would eventually be implemented.

4. The sharps injury prevention team wanted to trial both a passive and an active device (one-handed technique required to activate the device).

5. Reduction in needlesticks associated with the IV catheter device. We were interested in studies that had been published regarding the percentage of reductions in needlesticks with each particular IV catheter device.

6. No impending litigation with the device. One IV catheter device identified was in the process of litigation related to the technology of the device.

7. Feedback from community institutions on what brands worked.

8. Cost. This was a lower priority for our institution. Our sharps injury prevention team prioritized function of the device above the cost of the device.

Criteria used in physically examining IV catheters to ensure their appropriateness for front line staff device evaluation (Step 2)

1. After identifying two active designed catheters (one-handed technique required to activate safety shield) from two different manufacturers that met the screening criteria, Material Management arranged for both manufacturer representatives to present their products to the sharps injury prevention team. Standing members and ad hoc members attended the pre-pilot meetings. The manufacturer representatives provided sample IV catheters, demonstrated the use of each product, provided literature regarding reduction of needlesticks and studies on infection rates with their respective IV catheter and answered questions posed by committee members.

2. The members of the sharps injury prevention team conducted a hands on evaluation of each product, which included the following:
   - Activation of the safety features of the device
   - Simulated use of the product for starting IV's

3. Each member completed a pre-pilot evaluation form (see attachment 1) for each individual product. The pre-pilot form was designed to evaluate the safety, effectiveness, usefulness and usability of each product. Each criterion on the form was rated on a 5-point scale, with 1 being the

lowest (worst) score possible and 5 being the highest (best) score possible. In addition, each criterion was given a weight as to the importance of the feature. A 5-point scale was used; with 1 being the lowest (worst) score possible and 5 being the highest (best) score possible. The weighted score for each criterion was calculated by taking each score (1 through 5) multiplied by the weight score (1 through 5). All the weighted scores were added and divided by the number of criteria to calculate the total average score for each pre-pilot evaluation form.

4. A completed form was collected from each clinical member for each product evaluated and the results were analyzed and reported as follows:

   - A product receiving an overall score in the 1 or 2 range indicates significant problems with the usefulness or usability of the product. A product with a score in this range does not meet clinical criteria for use in our organization. If all products evaluated were in this range, we would attempt to identify and evaluate additional products in the same category.

   - A product receiving an overall score of 3 would be scheduled for a larger evaluation by front line clinical staff, if it were the only safer device in its category. If there was another functionally equivalent product or products that received a higher score (4 or 5) the product receiving a 3 would not be further evaluated.

   - A product receiving an overall score of 4 or 5 meets initial clinical criteria for use in our organization. In the case where two products from a single manufacturer or two products from two different manufacturers both received a 4 or 5 score on the pre-pilot evaluation, both products would be scheduled for a larger scale front line staff clinical evaluation.

   The weighted scores for the pre-pilot evaluation on the two active IV catheters that were selected were 4.58 and 4.00. Both products evaluated were selected for front line staff evaluation, based upon our scoring criteria.

Lessons learned during the process of identifying (step 1) and screening (step2) IV catheters

An oversight by the team was that not all available IV catheters were identified for consideration at the beginning of the pre-pilot evaluation process. One manufacturer had a shielded IV catheter that required activation that was not initially reviewed, although their passive device was

evaluated. Also, due to the dynamic safety device market, a new passive IV catheter began to be marketed after the initial pre-pilot evaluation was completed.

The team originally had wanted to pilot one active and one passive device. However, after comparing the passive and active device of each manufacturer and discussing the risk/benefits of the two devices of each manufacturer, both active devices were selected for the pre-pilot evaluation. The two passive devices were not selected, as they did not meet the pre-screening criteria. One device was not going to be available for several more months and the team wanted to proceed with the evaluation. The other passive device was not available in a 24-gauge size and the studies indicated that there was less reduction in needlesticks associated with the passive device than the manufacturer's active device.

Physically examining the devices took longer than the team had expected. We had allotted one and one-half hours for two vendors to each present their IV catheter product. Sixteen members were present at this meeting. There were many questions raised when the team members manipulated the devices that the representative had to respond to.

Advice about what our organization would have done differently if we were to begin this process again

- The chairperson should ensure all IV catheter devices currently available are pre-screened by the team. Ensure clarity to Material Management to search for all passive and active devices.

- Schedule pre-screening of all active and passive devices at one time or at two consecutive monthly meetings. This would have shortened the timeframe between the pre-pilot and pilot evaluation.

- Review only those products that are currently available on the market. Deciding to review a new device that was not yet on the market delayed beginning our pilot evaluation. However, based upon one's pre-pilot evaluation results, if the scores were low, reviewing the market again for newer devices may be beneficial. The organization would need to weigh the advantages and disadvantages of another pre-pilot evaluation. A review of safer medical devices each year would provide the opportunity to evaluate newer devices that have entered the market.

- Two hours would have been more appropriate for physically examining two IV catheter devices. The time needed to evaluate a safer device would depend upon the device being evaluated and the number of

devices evaluated (e.g., shielded scalpel pre-pilot evaluation took one hour for two devices).

Staff Hours

Type of Staff	Hours Spent on Phase 3
Management	16.5
Administrative	50
Front-line	20.5
Total	87

Other, non-labor items:

Item
Copying

Engineering Controls Evaluation Committee (ECEC)
Pre-Pilot Product Evaluation

A. Current Product to Be Replaced_____ Matkon #_____
B. Name of new product to be evaluated_____
C. Manufacturer of New Product_____
D. Description of Use_____

E. Where would product be used? ☐ Throughout Acute Care ☐ LTC

☐ OR ☐ Lab ☐ Ambulatory Care ☐ Specialty ☐ Home Health

1. Has the device been rejected by ECEC in past? ☐ YES ☐ NO

		Score (Disagree…Agree)	Weight	Weighted Score
2.	The product meets infection control standards and other regulatory requirements……	N/A 1 2 3 4 5	(5)	_____
3.	The device is compatible with products currently in use…….	N/A 1 2 3 4 5	(4)	_____
4.	The device is a passive safety mechanism……	N/A 1 2 3 4 5	(5)	_____
5.	The safety mechanism can be activated with one hand……	N/A 1 2 3 4 5	(5)	_____
6.	Use of the product requires use of the safety feature…….……	N/A 1 2 3 4 5	(5)	_____
7.	The user can tell when the safety mechanism has been activated…….	N/A 1 2 3 4 5	(4)	_____
8.	Once engaged, the safety mechanism locks in place…….	N/A 1 2 3 4 5	(5)	_____
9.	Minimal changes in technique and use are required…….	N/A 1 2 3 4 5	(3)	_____
10.	The device is easy to use……	N/A 1 2 3 4 5	(4)	_____
11.	A minimal number of parts/pieces are required to use the system/device……..	N/A 1 2 3 4 5	(3)	_____
12.	The safety device **does not** interfere with the intended use……	N/A 1 2 3 4 5	(5)	_____
13.	Documentation is available on patient discomfort…….	☐ YES	☐ NO	
	A. Patient discomfort **is not** increased……..	N/A 1 2 3 4 5	(4)	_____
	B. Bloodstream infections……	N/A 1 2 3 4 5	(5)	_____
	C. Patient Injury……	N/A 1 2 3 4 5	(5)	_____
14.	The product is available in typical size ranges……	N/A 1 2 3 4 5	(4)	_____
15.	Product representatives are available to educate and demonstrate devices at all locations…….	N/A 1 2 3 4 5	(5)	_____

Phase 3: Identify and Screen Safer Medical Devices

		L **Score** J Disagree…..Agree	**Weight**	**Weighted Score**
16.	The manufacturer has adequate product and supply capability …….	N/A 1 2 3 4 5	(5)	_____
17.	The product meets contract compliance……..	N/A 1 2 3 4 5	(2)	_____
18.	The cost is acceptable……..	N/A 1 2 3 4 5	(3)	_____
19.	Does the device significantly minimize or eliminate the risk of needlestick injury to the user and others before, during and after the use?	☐YES	☐NO	
	TOTAL AVERAGE SCORE			

DIRECTIONS: For each statement that is scored one through five, multiply the score by the weight. Add up these numbers and divide by 19 to calculate the total average score.

Appropriate for piloting [ ] On hold [ ] Rejected [ ]

Comments: _____

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